FEB 7 2000

K000149

USBiomaterials

510(k) Summary

General Information

Classification Name:	Endosseous Implant for Bone Filling and/or Augmentation
Common Name:	Bioglass® Synthetic Bone Graft Particulate
Trade Name:	Novabone™
Submitter's Name :	USBiomaterials Corporation
Address:	One Progress Boulevard, #23 Alachua, FL 32615
Telephone:	(904) 462-7660
Facsimile:	(904) 462-7605
Contact:	Albert Fosmoe II, Director of Quality Assurance and Regulatory Affairs
Date of Summary:	January 17, 2000

Device Description

Novabone™ is a synthetic osteoconductive particulate bone/void filler that is intended for oral/maxillofacial and dental intraosseous defects use. The material composed of Bioglass® (24.5 wt % CaO, 24.5 wt % Na_2O, 45 wt % SiO_2, 6 wt % P_2O_5) with a particle size range of 90-710 μm. It is supplied sterile in a Tyvek sealed PET-G cup that is protected by a shrink-wrapped cardboard box or polyethylene box. It is mixed with sterile water, saline, or the patient's own blood to form a wet sandy paste that is applied to the defect.

Predicate Device

Novabone™ is substantially equivalent to the legally marketed unmodified device named PerioGlas®

Intended Use

Novabone™ is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects including:

- Periodontal Defects
- Ridge Augmentation
- Extraction Sites
- Cranio-facial Augmentation
- Sinus Lifts
- Cystic Defects

Device Testing

The clinical performance of this device was previously evaluated in K992416. Packaging and labeling verification testing resulting from FMEA risk analysis was completed following design control.

Conclusions

Novabone™ devices continue to be safe and effective following modifications to include polyethylene outer packaging and a change in brand name.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

Mr. Albert Fosmoe II
Director of Regulatory Affairs
USBiomaterials Corporation
One Progress Boulevard, #23
Alachua, Florida 32615

Re: K000149
Trade Name: Novabone™ - Bioglass® Bone Graft Particulate
Regulatory Class: Unclassified
Product Code: LYC
Dated: January 18, 2000
Received: January 19, 2000

Dear Mr. Fosmoe II:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000149

Device Name: Novabone™

Indications For Use:

The intended use of Novabone™ is to provide a safe, biocompatible synthetic bone graft material for oral/maxillofacial and dental intraosseous defects use. It is to be used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (DFDBA demineralized freeze dried bone) or may be mixed with each as a bone graft extender. Typical uses include:

- Periodontal/Infrabony defects
- Ridge augmentation
- Extraction sites
- Cranio-facial augmentation
- Cystic cavities
- Sinus lifts

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000149

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)